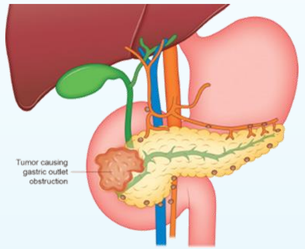
Enteral Isolation Device: Improving Palliative Treatment of Gastric Outlet Obstruction (GOO) by Establishing Endoscopic Ultrasound-Guided Gastrojejunostomy (EUS-GJ) as the Standard of Care

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Background on Gastric Outlet Obstruction (GOO)

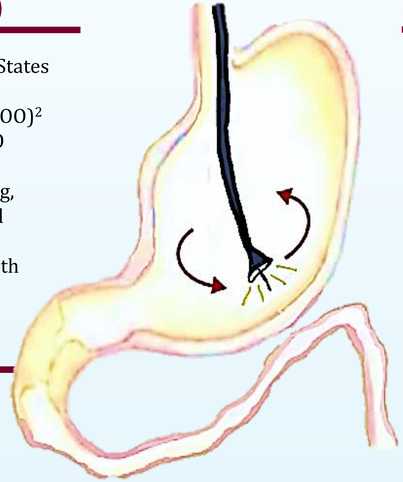


- 36,000 cases of GOO in the United States per year[1]
- 50-80% of GOO are malignant (MGOO)[2]
- 6 month mean survival from MGOO symptom onset
- Symptoms include nausea, vomiting, weight loss, malnutrition, pain, and dehydration
- Treatment of MGOO is palliative with stenting or gastrojejunostomy

Comparison of Treatment Options for MGOO

There are three main treatment options for MGOO which are compared in the table below:

Criteria	Endoscopic Stenting	Surgical GJ	Endoscopic GJ
Photo of Procedure			
Average length of stay in hospital	1 day	21 days	1-2 days
Reoperation rate	20-30%	7%	3%
Adverse events	40%	41%	16%
Technical success rate	90%	100%	92%
Clinical success rate	76%	94%	90%

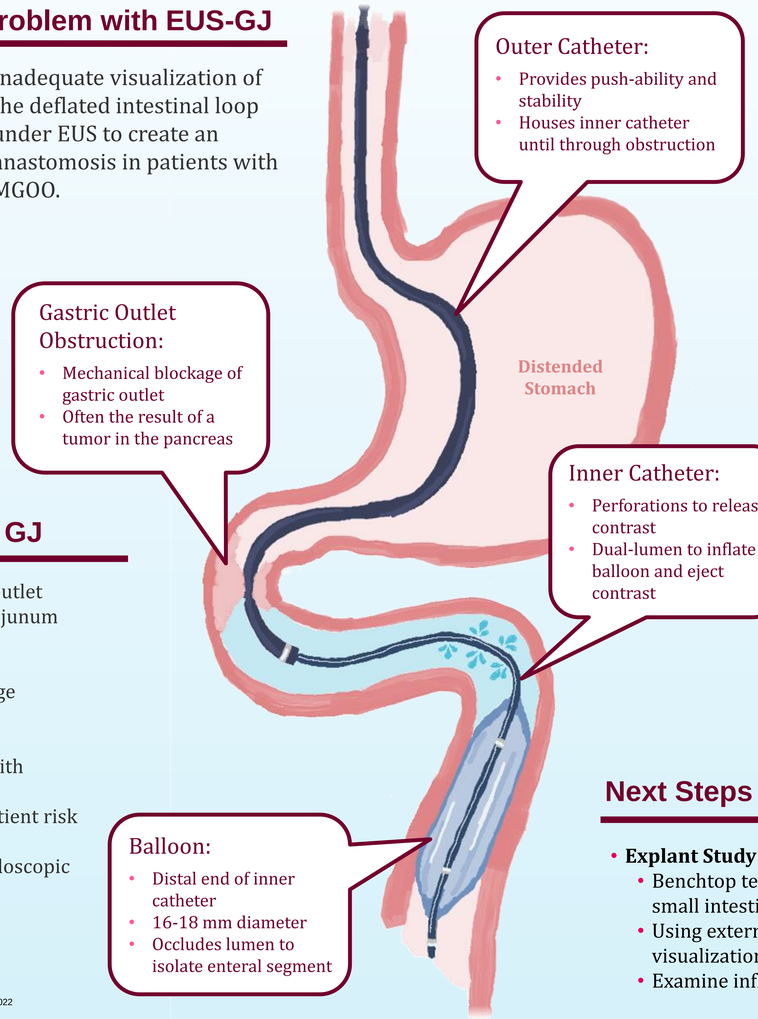


Endoscopic Ultrasound-Guided GJ

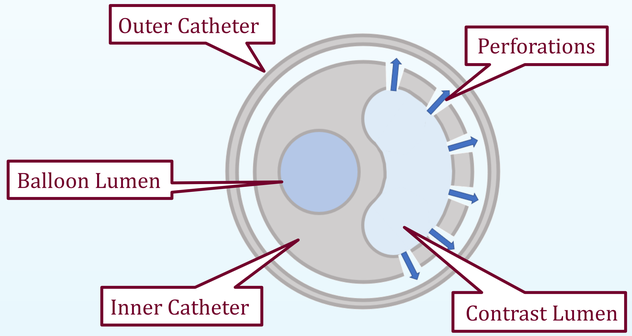
- Minimally invasive technique to bypass gastric outlet through connection between the stomach and jejunum
- Puncture performed endoscopically creating an anastomosis
- Lumen apposing stent placed to maintain passage
- Ultrasound scope is used to visualize during the procedure
- Sometimes off-label devices are used to assist with visualization
- Clinical outcomes on par with surgical GJ but patient risk is significantly reduced
- EUS-GJ has minimal hospital stays similar to endoscopic stenting

Problem with EUS-GJ

Inadequate visualization of the deflated intestinal loop under EUS to create an anastomosis in patients with MGOO.



The Enteral Isolation Device



- Device consists of a dual-lumen catheter with an attached balloon and small perforations proximal to the balloon
- One lumen is used to inflate the balloon, and the other lumen supplies contrast and water that is ejected from the perforations
- With jejunal segment inflated proximal to the balloon, it can be identified easily through endoscopic ultrasound
- Intestine inflation and visualization creates a large window for EUS guided anastomosis formation
- **Completed Testing**
  - Benchtop testing showing successful occlusion and demonstration of turbulent flow
- **Provisional patent filed**

Next Steps for the Enteral Isolation Device

- **Explant Study**
  - Benchtop testing within pig stomach and small intestine
  - Using external ultrasound to test visualization
  - Examine inflation of jejunal segment
- **Animal Study**
  - Assess prototypes in full pig model
  - Testing endoscopic ultrasound visualization
  - Evaluate use of device in full procedure

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Images:
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